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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Bacon *et al.*	Confirmation No.:	4238
Serial No.:	09/728,840	Art Unit:	1615
Filed:	December 1, 2000	Examiner:	Joynes, Robert M.
For:	PROLAMIN-BASED SUSTAINED-RELEASE COMPOSITIONS AND DELAYED-ONSET COMPOSITIONS	Attorney Docket No:	006544-999011 (Formerly: (9463-014-999)

DECLARATION OF LORENZO FABIANO BAGAROLLO UNDER 37 C.F.R. §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, LORENZO FABIANO BAGAROLLO, do declare and state as follows:

1. I am a citizen of Canada residing at 5330 18th Avenue, Montreal, Quebec H1X 2P1.

2. I received my Bachelor of Science Degree in Chemistry from Concordia University, Montreal, Quebec, in 1988. From 1967 to 1975, I worked in a quality control laboratory where I developed and optimized analytical procedures. From 1975 to 1978, I was employed as a Chemical Analyst at the pharmaceutical company Burroughs Wellcome, Inc. where my duties included improving and validating analytical procedures, as well as setting up a system for specification and methodology review. Between 1978 and 1983, I worked as a Technical Documentation Coordinator and then as a Supervisor of Special Projects at Burroughs Wellcome, Inc. From 1983 to 1995, I was the Manager of Development Laboratories at Burroughs Wellcome, Inc. where I created, developed and organized the formulation and analytical laboratories. From 1995 to 1996, I was the Manager of Pharmaceutical Development at Ciba Geigy Canada, Inc. where I developed a product for the world market according to international and FDA requirements. Between 1996 and 2003, I was the Manager of Product and Process Development at Wyeth-Ayerst Canada, Inc. where I built the scientific/technical basis for the optimization of film coating and contributed to the launch of more than 25 new products for Canada, without any market failures. I am currently employed at Labopharm, Inc., where I hold the position of Director of Galenics and

Formulation development. Further details of my experience are set forth in my curriculum vitae, attached hereto as Exhibit 1.

3. I have read and am familiar with the above-captioned '840 application, the February 26, 2003 non-final Office Action, the November 19, 2003 non-final Office Action, United States Patent 2,895,880 to *Rosenthal* (the "*Rosenthal*" patent), United States Patent 5,846,563 to *Baichwal* (the "*Baichwal*" patent), and United States Patent 5,356,467 to *Oshlack et al.* (the "*Oshlack*" patent) cited therein. I understand the Examiner has rejected claims 1, 3-8, and 18 as obvious under 35 U.S.C. § 103(a) over *Rosenthal* in view of *Baichwal*. I also understand the Examiner has rejected claims 9-17 and 19 as obvious under 35 U.S.C. § 103(a) over *Oshlack*.

4. One of ordinary skill in the art would not expect to achieve a sustained-release composition by adding the gelling agent disclosed in *Baichwal* to the composition described by *Rosenthal* so that the hydrophobic material is present in an amount from about 30% to about 70% by weight of the composition and the hydrophilic material is present in an amount of from about 5% to about 20% of the total weight of the composition since, based upon the teachings of *Baichwal*, the hydrophilic matrix would be disrupted.

5. One of ordinary skill in the art would recognize that *Oshlack* teaches that "[t]he upper limit of zein in the zein dispersions of the [*Oshlack*] invention are zein concentrations of about 10% w/v." (Col. 6, lines 26-28). *Oshlack* further teaches that his invention "is related to an aqueous dispersion of zein, the aqueous dispersion comprising from about 0.1 to about 10 percent zein." (Col. 3, lines 54-57). *Oshlack* discloses that "[h]igher concentrations have been found to result in the formation of agglomerates." (Col. 6, 28-29). However, the present invention, as presented in claim 9, comprises one or more prolamins in a critical amount of about 30% to about 100% of the total weight of the coating.

6. I declare further that all statements made in this Declaration of my own knowledge are true and that all statements made on information and belief are believed to be true and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: May 17-2004

Lorenzo Fabiano Bagarollo

LORENZO FABIANO BAGAROLLO

5330 18th Avenue, Montreal, Quebec H1X 2P1 Residence: (514) 729-0689

PROFILE

Dynamic overview of the pharmaceutical industry with 37 years of experience in the areas of product development, from specification, analysis and formulation development. Versed in process optimization and validation. Proven record in team building and development of pharmaceutical quality systems. Demonstrated ability for coaching all levels of scientific specialists. Capable of creating lasting synergy between people of diverse background expertise.

Languages (written and spoken fluently): English, French and Italian.

PROFESSIONAL EXPERIENCE

LABOPHARM INC. **2004 – present**

DIRECTOR, GALENICS & FORMULATION DEVELOPMENT

Reporting to the Vice-President of Research & Development.

- Directing a team of 10 formulation scientists for the development of specialty products using sustained release technologies.

WYETH-AYERST CANADA INC. **1996 – 2003**

MANAGER, PRODUCT & PROCESS DEVELOPMENT

Reporting to the Director of Technical Services, responsible for formulation and process development as well as for production technical support. Member of the WACI and WHR Validation Steering Committee.

- Introduced a new Multi-Project Management System.
- Developed the Product and Process Development Systems and a staff of 13 scientists/specialists, according to state-of-the-art development and CGMP requirements.
- Contributed to the launch of more than 25 new products for Canada, without any market failures.
- Supported existing formulations and daily production.
- Developed industrial study relationships with the University of Sherbrooke Engineering Faculty. Results: Staff obtained 1 MSc in the science of powder segregation and behaviours. One more MSc. Student to start in 2004.
- Built the scientific/technical basis for the optimization of film coating.
- Started to build the basis of Process Automated Testing (PAT) for product uniformity.
- Supported the practical introduction of statistical experimental design (DOE) for product development.
- Established the basis for scientific technological transfer of production technical operations.

CIBA GEIGY CANADA INC. **1995 – 1996**

MANAGER, PHARMACEUTICAL DEVELOPMENT

Reporting to the Vice President of Operations, responsible for formulation and process development, production scale-up, process optimization, process validation and a pre-market stability program, with a staff of 10 scientists/specialists.

- Successfully integrated into the Management Committee.
- Developed a new Multi-Project Management and Resource Allocation System for a total of 60 simultaneous projects.
- Participated in the strategic planning of the company.
- Developed a product for the world market according to international and FDA requirements.

B.W. INC. **1975 – 1995**

MANAGER, DEVELOPMENT LABORATORIES *1983 – 1995*

Reporting to the Senior Director of Quality Assurance and Development, who reported directly to the President, responsible for formulation, analytical and specification development, validation, stability programs, as well as information systems LIMS and CANSIS (Stability).

- Created, developed and organized the formulation and analytical laboratories, resulting in the launch of several new products, the acquisition of an incremental business of $12M and the support of $20-30M in sales per year of existing business.
- Introduced a new Multi-Project Management/Planning and Resource Allocation System for a total of 50 simultaneous projects.
- Participated in the creation of a universal computer system for the life cycle of a product, from molecular stage to finished product.
- Successfully executed the project of analytical unit certification of Q.A., based on ISO 9000 standards and mode. Our unit was the first in Wellcome worldwide to achieve this accreditation, paving the way for other Wellcome units and resulting in savings through group and staff reduction in the UK.
- Successfully executed the project for the re-engineering of Quality and Development, resulting in an 18% reduction in establishment and a 12% cost reduction, for an annual saving of $500,000; this eliminated duplication and empowered operations personnel in maintaining service to customers.
- Led Quality and Development as well as Operations teams in the preparation of FDA pre-approval audits, resulting in export business to the U.S. market. Hosted audits, HPB, FDA and third-party contracts. Supported Quality Assurance and Operations in all areas.
- Acted as official deputy for the Senior Director of the Quality and Development unit in the absence of the unit's Senior Director.

SUPERVISOR, SPECIAL PROJECTS *1980 – 1983*

Supervise the documentation review section and stability testing laboratories, with a staff of five. Responsible for internal and external audits.

- Set up and developed the Special Projects section, which became the embryo of the development laboratories.
- Repatriated the stability program that was formerly carried out in the UK.
- Set up laboratories and systems.
- Further developed the documentation review section, from which became the Quality Assurance Audit department.

TECHNICAL DOCUMENTATION COORDINATOR *1978 – 1980*

Revise batch record documentation for the purpose of product release.

- Set up and developed a system for the collection and centralization of all batch records for the purpose of reviews against CGMP in conjunction with batch release.

SENIOR CHEMICAL ANALYST *1977 – 1978*

Responsible for the testing of finished products and for the optimization of analytical procedures.

- Improved and validated analytical procedures, as well as set up a system for specification and methodology review.
- Optimized laboratory efficiency and started the implementation of HPLC technology.
- Trained analysts on the job.

CHEMICAL ANALYST *1975 – 1977*

Responsible for the testing of finished products.

- Acquired chemical laboratory and quality control skills

ACCURATE MANUFACTURING CHEMISTS INC. **1967 – 1975**

ASSISTANT TO THE QUALITY CONTROL MANAGER

Responsible for the testing of raw and finished products, for specification and product development, and for production troubleshooting.

- Kept the Quality Control laboratory in full operation while successive changes of Quality Control managers developed several multivitamins formulations.
- Developed and optimized analytical procedures.

EDUCATION

BACHELOR OF SCIENCE (CHEMISTRY) – Concordia University, Montreal, Quebec

PROFESSIONAL DEVELOPMENT

- GRID
- ISO 9000 and Total Quality
- BISADA – Business Simulation
- R&D Management – Concordia Centre of Management Studies
- Pharmaceutical Project Management – Centre for Professional Advancement
- Management of Change – Mica Management
- Finance for Non-Financial Managers – McGill University, and
- Other relevant courses and training seminars.